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August 3, 2000

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

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Re: Docket No. 98N-0359 - Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for FY2001

I wish to comment on the establishment of program priorities in CFSAN for FY2001. I have been an industrial scientist active in the baby feeding industry for over thirty years, a member for almost ten years of the Technical Advisory Group that once served the Committee on Nutrition of the American Academy of Pediatrics and a Charter Member of the National Organic Standards Board appointed by the Secretary of Agriculture. Most recently I was privileged to serve as a member of the United States Delegation to the 22nd meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in June 2000 at the invitation of the Chief U.S. Delegate to CCNFSDU, Dr. Elizabeth Yetley of CFSAN.

In response to the request of the Food and Drug Administration (FDA) for public comments concerning the establishment of program priorities and work product expectations, I reviewed the CFSAN document entitled "2000 CFSAN Program Priorities" on the CFSAN web page. Focusing on the critical resource allocation question of where CFSAN can do the most good for consumers, I propose that the Agency adopt the following approach to address Strategy 2.2 - Nutrition, Health Claims and Labeling, "B" List item Nr. 9, "Initiate a review of food fortification guidelines."

The Fortification Policy codified as 21CFR104.20 needs revision. As currently formulated and interpreted, it creates significant obstacles to rational fortification of foods, because of its 'wholesale' condemnation of certain classes of foods as inappropriate vehicles for delivering nutrients to target populations. The Policy specifically states: "... nor does it (FDA) consider it appropriate to fortify fresh produce; meat, poultry or fish products; sugars; or snack foods such as candies and carbonated beverages." This Policy has been accepted and interpreted by FDA's sister food regulatory agency, the Food Safety and Inspection Service of the U.S. Department of Agriculture (FSIS), to prohibit nutrient fortification of meat and poultry products, including those intended for older infants. Older infants are at risk of iron deficiency. Meat-containing baby foods are excellent vehicles for iron fortification and are used for this purpose in Europe, with clinical substantiation of the nutritional benefit. Ironically, FSIS does allow addition to meat and poultry products of 'nutrients' that have a recognized technological function in the food itself (such as ascorbic acid as a curing accelerator) but does not allow addition of 'nutrients' for nutritional purposes unless required by regulation.

To modernize the Fortification Policy and to minimize the work required of CFSAN, while adhering to the Agency's criterion of consistency with generally recognized

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principles of sound science, I propose that FDA consider adopting as its Fortification Policy, the current Codex General Principles for the Addition of Essential Nutrients to Foods.

The Codex General Principles for the Addition of Essential Nutrients to Foods can be accessed at <<http://www.fao.org/docrep/w2840e/w2840e04.htm>>. A copy accompanies this letter. The basic principles are entirely consistent with sound science and the reasoned approach endorsed by the U.S. Food and Nutrition Board of the National Research Council and cited in 1974 in the preface of the booklet "Proposed Fortification Policy for Cereal-Grain Products." They are in essence the principles used most recently by the Agency in its adoption of a requirement for folic acid fortification of cereal and grain products.

Thus, the General Principles state that "Any fortification programme should meet the following conditions:

- "There should be a demonstrated need for increasing the intake of an essential nutrient in one or more target groups. This may be in the form of actual clinical or sub-clinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiency likely to develop because of changes taking place in food habits;
- "The food selected as a vehicle for the essential nutrients should be consumed by the population at risk;
- "The food selected as a vehicle for the essential nutrient(s) should be stable and uniform and the lower and upper levels of intake should be known;
- "The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk;
- "The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food."

Providing the information required to address these criteria in a comprehensive manner should be enough to justify nutrient fortification of a certain food.

Note that the majority of delegations at the 22nd meeting of the CCNFSDU concluded that these General Principles were appropriate and not in need of revision. Adoption of the Codex General Principles would further the objective of harmonization of national regulations with Codex standards.

I hope that the Agency finds this suggestion a useful approach to help it achieve its program goals.

Sincerely,



Richard C. Theuer, Ph.D.



IMPACT OF LEGISLATION

General principles for addition of nutrients to foods Consideration of additional requirements

Nutrients are increasingly being added to foods for a number of reasons and this tendency raises the issue of the regulation of such practices. Discussion on the impact of legislation was based on the working paper entitled 'Impact of Legislation on Food Fortification Practices' (CONFORT 3).

It should be stressed here that there is a substantial body of legislation at the national level, as well as Codex international recommended standards which are applicable to all food products. The Consultation stressed that these same requirements must in general apply also to foods to which nutrients are added. However, some specific issues related to the practice of addition of nutrients to foods may require additional legal provisions. Such provisions, however, should cover the subject of the addition of nutrients horizontally across a range of foods. Vertical (product specific) legislation should be discouraged unless strictly necessary.

General principles for addition of nutrients to foods

At the present stage of world trade development, the existence of international provisions pertaining to the addition of nutrients to foods are necessary in order to facilitate trade in such products. Within the FAO/WHO Food Standards Programme, the Codex Alimentarius Commission has adopted "General Principles for the Addition of Essential Nutrients to Foods".

According to these General Principles, essential nutrients may be added to food in order to achieve any of the following: restoration of nutrients lost during processing; nutritional equivalence of substitute foods; fortification; and ensuring the appropriate nutrient composition for a special purpose food. The basic principles for the addition of essential nutrients to foods, as stated by the Codex Alimentarius Commission are:

1. The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet;
2. The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient;
3. The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use;

4. The essential nutrient should be biologically available from the food;
5. The essential nutrient should not impart undesirable characteristics to the food and should not unduly shorten the food shelf life;
6. Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner;
7. Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food;
8. The additional cost should be reasonable for the intended consumer;
9. Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in the foods should be available;
10. When provision is made in food standards, regulations or guidelines, for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients which are to be considered or be required and the levels at which they should be present in the food to achieve their intended purposes.

As stated previously, the Codex definition of fortification is, "...the addition of one or more essential nutrients to a food whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups...". Within the above General Principles outlined by the Codex, nutrient addition for purposes of fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations and the food consumption patterns in the area. Any fortification programme should meet the following conditions:

- There should be a demonstrated need for increasing the intake of an essential nutrient in one or more target groups. This may be in the form of actual clinical or sub-clinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiency likely to develop because of changes taking place in food habits;
- The food selected as a vehicle for the essential nutrients should be consumed by the population at risk;
- The food selected as a vehicle for the essential nutrient(s) should be stable and uniform and the lower and upper levels of intake should be known;
- The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk;

- The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

Consideration of additional requirements

The Consultation felt that there were a number of issues related to food fortification which should be additionally considered:

Compulsory addition of nutrients

Such rules would be the responsibility of national authorities and respond to specific regional, national or even local situations. Specific provisions may address:

- Specific food vehicles to be chosen on the basis of the recommendations given above;
- Specific nutrients that may be added to these foods;
- Specific levels which would be appropriate for the situation.

Existing legislation currently pertaining to nutrient addition to selected food products in many countries are included in Annex 7.

The establishment of an advisory list of nutrients

The establishment of an advisory list of nutrients and nutrient compounds to be used in food fortification should be encouraged. The Consultation felt that the Advisory lists of mineral salts and vitamin compounds for use in foods for infants and young children detailed in the Codex Alimentarius Volume 4-1994, would be an excellent starting point. Such a list should be regularly updated taking into account new scientific and technological developments and data on safety, bioavailability, stability and other relevant data.

Foods to which nutrients may be added

The Consultation felt that a list of foods to which nutrients may be added should not be drawn. However, the selection of such foods should be guided by the principles set out in the appropriate Codex guidelines referred to above.

Levels of nutrients

The Consultation believed that minimum levels for the addition of nutrients should be set, in international recommended standards, according to the purpose of the addition. The setting of maximum levels, it was felt, should be considered for those nutrients for which there is evidence that excessive intakes would result in undesirable effects.

Labelling

It has already been stated that general labelling rules and specific rules on nutrition labelling should apply. A particular issue of interest is that of nutrition claims and health claims to be made for foods to which nutrients are added.

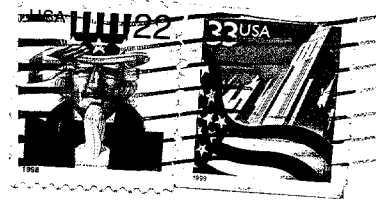
Experience has shown that the success of food fortification programmes can be enhanced by permitting the manufacturers to make relevant claims. Commercial realities would also advocate that such permission also be granted when nutrients are added voluntarily to foods. However, care should be taken that use of claims does not result in practices that could mislead or deceive the consumer or distort the true value of the fortification.

Given that the subject of health and nutrition claims on food labelling is currently being discussed within the Codex Alimentarius programme, the Consultation did not deem it appropriate to discuss it further. However, the Consultation recommended that Codex accelerate the resolution of this important matter.

Finally, the Consultation suggested that the extent of legislative measures to be developed should not be such as to make fortification practices cumbersome nor restrict communication on the availability of the fortified food. The legislative development process should involve extensive consultation with the scientific community, industry, consumers and other relevant, interested parties.



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